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(54) IMPROVEMENTS IN OR RELATING TO SOFT DRINKS CONTAINING ELECTROLYTES

(71) We, JOHNSON & JOHNSON, a Corporation organised under the laws of the State of New Jersey, United States of America, of 501 George Street, New Brunswick, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to powdered mixtures which can be reconstituted with water to form electrolyte drinks. More specifically, this invention relates to flavored, powdered mixtures which can be reconstituted with water to form flavored hypotonic drinks which are characterized by rapid gastric emptying into the system thereby providing excellent availability of water and electrolytes to the system.

Such drinks are desirable for all individuals who have undergone exercise, strenuous work or activity but are particularly recommended for athletes engaged in all levels of athletic training and competition. Athletes are particularly prone to exercise and heat-related illnesses, particularly those who are not in peak physical condition. The cause of such disorders may be traced directly to dehydration and loss of electrolytes from the body. During exercise or athletic competition, body activity greatly increases, resulting in the production of heat. Only about 25% of the energy generated is converted into useful work with the remaining 75% evolved as body heat and 80—90% of said body heat is dissipated by the evaporation of sweat. Since body temperature regulation has priority over the maintenance of the water and salt balance, sweating will occur and continue in an effort to maintain normal body temperature and this can result in dehydration and marked electrolyte losses. The most important electrolytes affected are the sodium, potassium, chloride and phosphate ions. It is not unusual for an athlete to lose about 5% of his body weight during two football practices occuring in a single day.

As a result of these effects on the body, three common exercise and heat-related disorders may occur; heat cramps, heat exhaustion and/or heat stroke. Heat cramps are characterized by painful skeletal muscle contractions and are the result of large sodium and chloride ion losses in both sweat and urine, and a possible potassium ion deficit.

Heat exhaustion occurs when losses of water and salts are high, resulting in a fall in the blood pressure, low cardiac output, and a high pulse rate due to the decrease in blood volume and extracellular fluid. The reduction in circulation leads to a rise in body temperature as the dispersion of heat becomes more difficult. Cell metabolism is upset when large amounts of water and potassium ions are lost from the cells. This loss of water and potassium ions is critical since potassium is necessary for the maintenance of heart muscle and skeletal muscle fiber tone. Heat exhaustion symptoms include profuse sweating, lassitude or fatigue, vomiting and fainting; all of which can occur when weight losses are about 5% of body weight or greater.

Heat stroke is the most dangerous form of heat injury. It is the result of high body temperatures in the region of 105—106°F and is classified as a medical emergency. At these temperatures, the thermal regulatory mechanism in the brain breaks down due to cell damage which may be permanent if the temperature is not reduced rapidly. Heat stroke symptoms include headache, weakness, vertigo, and dry skin. When the loss of body weight exceeds 10%, there is a good chance of circulatory collapse and death. Body temperatures must be reduced as fast as possible and fluids should be provided intravenously and by mouth, if possible.

These and other physical disorders have long been recognized as possible highly undesirable effects of strenuous exercise or athletic competition and various methods of minimizing the dangers of such effects have been proposed including attaining the proper physical conditioning and utilizing the proper clothing and/or protective equipment. In

recent years, the time-accepted tradition of not drinking large amounts of liquids to satisfy one's thirst during or immediately after strenuous activity has come under question and led to the introduction of various "thirst quencher" or so-called "electrolyte" drinks. Such products have as their avowed purpose the resupply of water and electrolytes to the system. The products presently available have serious deficiencies in fully satisfying this purpose. For example, some products are formulated in a manner which prevents their emptying from the stomach into the bloodstream quickly while other formulations are unpalatable or leave a bitter aftertaste which results in hindering rather than encouraging one to fully utilize such products and thus one does not obtain sufficient quantities of water and electrolytes to replace that which has been lost.

It is therefore a general object of this invention to provide a dry mixture suitable for reconstituting with water into a drink which overcomes the above-discussed negatives of the products that have previously been available to the consumer.

It is another object to provide a dry mixture suitable for reconstituting with water into a hypotonic drink characterized by fast gastric emptying resulting in rapid availability of water and electrolytes to the system.

It is a further object of the present invention to provide a dry mixture suitable for reconstituting with water into a flavoured hypotonic drink with a relatively low level of sweetening agents and a satisfactory taste.

According to the invention we provide a hypotonic drink which comprises sodium ions, potassium ions, chloride ions and phosphate ions and a sweetening agent and has an osmolarity of from 80 to 200 mOsm.

The invention further provides a dry powdered mixture adapted by virtue of its composition for reconstituting with water to form a hypotonic drink comprising specific amounts of salt electrolytes and sweetening agents and having the specific osmolarity mentioned in the preceding paragraph.

An important characteristic of the drinks of the present invention is the tonicity or, as it is often called, the osmolarity of said drinks. For the purposes of describing the present invention, these terms will be used interchangeably. Tonicity is a measure of the osmotic pressure of a solution relative to the osmotic pressure of the blood fluids. An isotonic solution is a solution of the same tonicity (osmotic pressure) as a normal saline solution and therefore is of the same tonicity as blood serum. A hypertonic solution is a solution of greater tonicity than an isotonic solution whereas a hypotonic solution is a solution of lower tonicity than an isotonic solution. It has unexpectedly now been found that the tonicity of electrolyte drinks is particularly critical with respect to providing rapid gastric emptying of the solution from the stomach into the bloodstream. Thus, it appears that the tonicity (osmolarity) of any drink solution is directly related to the rate at which such a solution can get from the stomach into the bloodstream. Most commercially available electrolyte drinks are either isotonic or hypertonic and tend to empty relatively slowly from the stomach. Aside from the slower availability of the needed water and electrolytes to the system, the slower emptying from the stomach also results in more fluid remaining in the stomach of the individual who has to rehydrate rapidly and this discourages the intake of additional fluid resulting in less of the needed water and electrolytes getting into the system to replace what has been lost as a result of sweating.

We have now unexpectedly found that an osmolarity of from 80 to 200 mOsm per liter is required in order to provide emptying of the solutions from the stomach into the bloodstream in a rapid manner to provide the needed electrolytes and water to the system. A preferred osmolarity is from 90 to 130 mOsm. Most commercially available products have osmolalities significantly higher than the above levels.

It has now been found that by controlling the amount of electrolytes that are included in the mixtures of the present invention and by limiting the amounts of sweetening agents added to such mixtures, the osmolarity of the resulting solutions can be maintained within the desirable levels thereby resulting in fast gastric emptying and rapid availability of water and electrolytes to the system. It has also been found that by utilizing lower than normally suggested levels of sweetening agents in such mixtures, the osmolarity of the resulting solutions can be regulated such that the gastric emptying rate is not adversely affected although a pleasantly tasting, non-bitter drink is still provided.

The dry mixtures of the present invention suitable for reconstitution with water should contain sodium potassium, chloride and phosphate ions as electrolytes in amounts sufficient to provide adequate replacement of the normal levels of these components in the body as well as a specific amount of suitable sweetening agents, optionally with citric acid, suitable flavorings and coloring agents. The sodium and potassium salts useful in this invention can be, for example, chlorides, citrates, or phosphates, although it would be desirable for at least some of these salts to be the chlorides and phosphates since such would provide the chloride and phosphate ions in addition to supplying the sodium and potassium ions.

In order to satisfy the objectives of the present invention, it is necessary for the

electrolytes to be present in specific amounts. The sodium ion should be present in a range of from 10 to 35 mEq per liter, the potassium ion in a range of from 0.5 to 20 mEq per liter, the chloride ion in a range of from 10 to 35 mEq per liter and the phosphate ion in a range of from 1 to 15 mEq per liter. Problems may develop if amounts of these electrolytes outside the ranges are utilized, for example, if too much sodium ion content is present in the dry mixture, the resultant solution may have a salty taste and may cause some stomach irritation. If too much chloride ion or phosphate ion is present in the dry mixture, the resultant solutions may have flavor problems.

The sweetening agents which can be utilized in the present invention include both the natural and artificial sweeteners. The natural sweeteners include sugars such as glucose, sucrose, lactose and maltose. The total concentration of the natural sweeteners should be from 1 to 54 m. moles (millimoles) per liter since if amounts greater than 54 m. moles per liter are utilized the osmolarity would be adversely affected. Thus, for example, the glucose can be utilized in a range of from 0 to 10 g. per liter and the sucrose in a range of from 0 to 20 g. per liter as long as the total concentration is not greater than 54 m. moles per liter.

Part of the natural sweetening agents can be replaced by artificial sweetening agents such as the saccharins, cyclamates where permitted, dipeptides such as the dipeptide sold under the trademark Aspartame by G. D. Searle & Company. Specifically, sodium or calcium saccharin can be substituted for some of the natural sweetening agents to provide the desired sweetness without adversely affecting the osmolarity although use of too much of the artificial sweetening agents may cause flavor problems to the resulting drink.

It should be borne in mind that choosing the amounts of the above ingredients to be utilized requires a balancing of the desired features to be achieved. For example, in order to keep the osmolarity within the specific range to achieve rapid gastric emptying into the ssytem, the amount of sweetening agents must be limited and yet sufficient amounts must be utilized to provide a pleasant tasting drink in order to encourage its use. Thus, if excess chloride or phosphate ion is utilized, flavor problems may result requiring additional sweetening agents which may adversely affect the osmolarity. Therefore, the amounts of the required components of the mixtures of the present invention must be carefully maintained within the above limitations to achieve the desired results of the present invention.

Other components which can be utilized in the mixtures and drinks of the present invention include such components as are normally found in such compositions such as citric acid or the salts thereof, ascorbic acid, flavors, colorings. The citric acid can be present in the range of from 0—10 g. per liter and is utilized as an aid to develop the flavor of the mixture and resultant drink. Ascorbic acid provides a source of Vitamin C which is desirable. Flavors such as the citrus flavors, for example, orange, lemon, lemon-lime and the non-citrus flavors, for example, strawberry, punch and colorings such as United States FD&C Red #40 and FD&C Yellow #5, can be utilized where permitted to achieve the desired flavor and colors of the resulting drink.

The mixtures of the present invention can be prepared by conventional mixing and blending techniques utilizing standard equipment. The components are milled to a suitable size and then mixed and blended in the required amounts to form the mixtures which can then be reconstituted with water as desired.

EXAMPLE I

An orange flavored, powdered mixture in accordance with the present invention was prepared by milling the components through a No. 4 screen (U.S. Standard) and then blending the components for about 10 minutes in an ABBE blender to obtain a dry powdered mixture of the following composition:

	% w/w
Potassium chloride, granular	1.395
Sodium chloride, granular	4.736
Potassium phosphate, (monobasic) crystals	5.760
Sodium citrate, anhyd. powder	3.799
Sodium saccharin, powder	1.246
Ascorbic acid, granular	0.411
Glucose, USP. anhyd.	32.104
Sucrose, USP crystals	32.104
Citric acid, anhyd. gran.	15.570
FD&C Red No. 40	0.037
FD&C Yellow No. 5	0.037
Orange Flavor	2.801

EXAMPLE II

A punch flavored, powdered mixture was prepared in accordance with the procedure of Example I and was of the following composition:—

	% w/w
Potassium chloride, granular	1.355
Sodium chloride, granular	4.599
Potassium phosphate, (monobasic) crystals	5.598
Sodium citrate, anydhyd. powder	1.246
Sodium saccharin, powder	1,210
Ascorbic acid, granular	0.400
Glucose, USP, anhyd.	31.195
Sucrose, USP crystals	31.195
Citric acid, anhyd. gran.	18.155
Strawberry Flavor	1.210
Punch Flavor	1.210
FD&C Red No. 40	0.182

62.5 grams of this mixture is reconstituted with one U.S. gallon of water to form a pleasantly tasting punch-flavored hypotonic tonic.

EXAMPLE III

The composition of Example I and four commercially available "thirst quencher" drinks designated as A, B, C and D were reconstituted according to instructions. These drinks were then analyzed for sodium and potassium ion contents by means of flame photometry and for chloride ion content by means of potentiometric titration. The natural sweetening agent content was determined by standard glucose oxidation methods and the osmolarity of each of the solutions was determined by a depression of freezing point method. The results of these analyses are shown in Table I below:

TABLE I

Solution	Na+ (mEq/l)	K+ (mEq/l)	Cl− (mEq/l)	Osm (mOsm/l)	Natural Sweetening Agent (g/100ml)
A	26.3	0.6	21.5	294	4.1
B	15.3	8.4	17.0	281	4.9
C	26.3	2.4	16.0	319	6.6
D	17.5	1.4	17.0	258	4.7
E	23.0	9.3	14.8	118	1.3

As can readily be observed from the above results, although other compositions provide similar amounts of sodium, potassium and chloride ions, only solution E, the composition of Example I made up as a hypotonic drink provides a low sugar concentration and an osmolarity in the desired range in order to provide the desired rapid gastric emptying of the solution resulting in the fast availability of water and electrolytes to the system.

EXAMPLE IV

In order to demonstrate the rapid gastric emptying of the solutions of the present invention resulting in the fast availability of water and electrolytes to the system, the following test was conducted. Six men ingested 400 ml. of the solutions of Example III or 400 ml. of water and the gastric residue was measured by means of inserting a tube into the stomach and withdrawing the fluid therein 15 minutes later to determine the volume emptied from the stomach. The results are reported in Table II below:

TABLE II

Solution	Volume Ingested (ml)	Gastric Residue (ml)	Volume Emptied from Stomach (ml)
A	400	301	99
B	400	275	125
C	400	263	137
D	400	267	133
E	400	125	275
Water	400	187	213

As can readily be seen from the results above, the solution of Example I of the present invention empties significantly faster than the commercially available electrolyte drink solutions A, B, C and D tested above and even more than water alone. It would thus be apparent that the solutions of the present invention unexpectedly provide water and electrolytes to the system more rapidly than previously available products which is, as discussed above, highly desirable.

WHAT WE CLAIM IS:—

1. A hypotonic drink which comprises sodium ions, potassium ions, chloride ions and phosphate ions and a sweetening agent and has an osmolarity of from 80 to 200 mOsm.

2. A hypotonic drink according to Claim 1, wherein the sodium ion content is from 10 to 35 mEq per litre, the potassium ion content is from 0.5 to 20 mEq per litre, the chloride ion content is from 10 to 35 mEq per litre, the phosphate ion content is from 1 to 15 mEq per litre, and the sweetening agent is present in a concentration of from 1 to 54 millimoles per litre.

3. A hypotonic drink according to Claim 1 or 2, wherein the sweetening agent is a natural sweetening agent selected from sucrose, glucose or a mixture thereof.

4. A hypotonic drink according to Claim 3, wherein the natural sweetening agent is partly replaced by an artificial sweetener.

5. A hypotonic drink according to any preceding Claim, wherein the osmolarity is from 90 to 130 mOsm.

6. A hypotonic drink according to Claim 1, substantially as described in the foregoing Examples.

7. A dry powdered mixture adapted by virtue of its composition for reconstituting

with water to form a hypotonic drink as claimed in any of Claims 2 to 6.

8. A mixture according to Claim 7, substantially as described in the foregoing Examples.

For the Applicants:
CARPMAELS & RANSFORD,
Chartered Patent Agents,
43, Bloomsbury Square,
London, WC1A 2RA.

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